

*Sub
C
cont
B3*

flow carries at least one of the at least one source of peroxide and the at least one source of hypochlorite anion to the target site.

*Sub
C
B4*

31. (Amended) The method according to claim 30, wherein at least one of the aqueous solutions comprising the at least one source of peroxide and the at least one source of hypochlorite anion further comprises at least one pharmaceutically acceptable excipient.

*Sub
C
B5*

36. (Amended) A method of treating a target site in or on a mammal, comprising: administering at least one source of singlet oxygen, wherein the at least one source of singlet oxygen comprises superoxide.

REMARKS

Applicant submits this Amendment along with a Response to the Restriction and Election of Species Requirements set forth in the Office Action dated March 26, 2003. With this Amendment, claims 1-3, 5-9, 12, 31, and 36, are amended to even more clearly define the claimed invention, without changing the scope of the claims. Claims 1-46 are pending in this application.

Restriction

In the Office Action dated March 26, 2003, the Examiner required restriction under 35 U.S.C. § 121 between the following groups:

- I. Claims 1-18, 29-31, and 36, drawn to method and system of treating a target site in or on a mammal comprising superoxide or a source of peroxide and a source of hypochlorite anion;
- II. Claim 13, drawn to singlet oxygen produced by introducing into a mammal a source of peroxide and a source of hypochlorite anion;

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- III. Claims 19-28, drawn to an apparatus comprising a first reservoir of a source of peroxide, a second reservoir of a source of hypochlorite anion, and conduits leading to a delivery port for each reservoir;
- IV. Claim 32, drawn to a singlet oxygen producing composition comprising a source of peroxide, a source of hypochlorite anion, and excipients;
- V. Claims 33-35, drawn to a method of disinfecting or decontaminating an inert area comprising a source of peroxide, a source of hypochlorite anion, and excipients; and
- VI. Claims 37-46, drawn to a device for combining at least two fluid reactants.

In the Office Action, the Office states that inventions II and IV, and I and V are patentably distinct because they are related as product and process of use, and the process of use can be practiced with another materially different product and the product can be used in a materially different process. Office Action, pages 2-3. Inventions I and V are stated as being unrelated because they are not disclosed as capable of use together and have different modes of operation, i.e., mammals versus inert areas. *Id.* at 3. It is also stated that inventions I, and III and VI are patentably distinct because they are related as process and apparatus for its practice, and the process as claimed can be practiced by another materially different apparatus and the device as claimed can be used to practice another and materially different process. *Id.* It is further stated that inventions III and VI, and II and IV are patentably distinct because they are related as apparatus and product made, and the apparatus can be used for making a different product as the product as claimed can be made by another and materially different apparatus. *Id.* Finally, the Office states that the inventions have acquired a separate status in the art because of their recognized divergent subject

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matter, i.e., methods, products, and apparatuses, and constitute an undue burden on the Examiner. *Id.* at 4.

In response to the Restriction Requirement, Applicant provisionally elects to prosecute Group I, claims 1-18, 29-31, and 36, *with traverse*.

Applicant respectfully submits that while the reasons provided by the Office are factors in determining whether claims should be examined together, they are not the *only* factors. For example, it is respectfully submitted that the subject matter of all pending claims are sufficiently related that a thorough search of the subject matter of any one group of claims would encompass a search for the subject matter of the remaining claims. Thus, a search and examination of the non-elected subject matter with that of Group I would not place a serious additional burden on the Examiner. "If the search and examination of the entire application can be made without serious burden, the examiner must examine it on the merits, even though it includes claims to independent or distinct inventions." M.P.E.P. § 803 (emphasis added). It is respectfully submitted that this policy should apply in this application in order to avoid unnecessary delay and expense to Applicant and duplicative examination by the Office.

In view of the foregoing, Applicant respectfully requests the Office withdraw the restriction requirement and consider the pending claims together.

Election of Species

In the Office Action, the Examiner also required an election of species under 35 U.S.C. §121 of one of each of the following allegedly patentably distinct species: a target site, a peroxide source and a hypochlorite source, or superoxide.

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The election of species requirement is respectfully traversed. To be fully responsive, however, Applicant provisionally elects to prosecute claims directed to the target site species of a tumor; the subgenus of hypochlorite source and peroxide source, including the species of sodium hypochlorite and hydrogen peroxide. Claims 1-10, 12-16, and 29 of Group I are readable on the elected subgenus. Claims 1-4, 6-10, 12-16, and 29 of Group I are readable on the elected species. Applicant understands that upon the allowance of a generic claim, any non-elected claims depending from that claim or otherwise including all the limitations of that claim will be rejoined and entitled to consideration.

Applicant traverses the election of species requirement on the grounds that the Examiner has not shown that there would be a serious burden to examine all of the claimed species. See M.P.E.P. § 803. In fact, a thorough search and examination of both elected and non-elected species would not place any serious burden on the Examiner. Accordingly, Applicant respectfully requests that the full scope of the claimed species be examined in this application without an election of species requirement. At the very least, Applicant respectfully requests that the Examiner initially consider claims 1-18 and 29-31, which involve the administration of a hypochlorite source and a peroxide source.

If the Examiner chooses to maintain the election of species requirement, however, and should the elected species be found allowable, Applicant expects the Examiner to continue to examine the full scope of the claimed subject matter to the extent necessary to determine the full scope of the patentability thereof, i.e., extending

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the search to the non-elected species, as is the duty of the Examiner according to
M.P.E.P. § 803 and 35 U.S.C. § 121.

Conclusion

In conclusion, Applicant respectfully requests that the Examiner withdraw the restriction and election of species requirements and consider all of the pending claims together.

Please grant any extensions of time required to enter this response and charge any additional required fees to our Deposit Account No. 06-0916.

Respectfully submitted,

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APPENDIX

This Appendix is being provided in accordance with 37 C.F.R. § 1.121(c)(1)(ii). This Appendix is not intended to form part of the application.

Amendments to the Claims:

1. (Amended) A method of treating a target site in or on a mammal, comprising: administering at least one source of peroxide and at least one source of hypochlorite anion to the target site to be treated and allowing the at least one source of peroxide and the at least one source of hypochlorite anion to react to produce singlet oxygen.
2. (Amended) The method according to claim 1, wherein the at least one source of peroxide comprises at least one of hydrogen peroxide, alkyl hydroperoxides, or metal peroxides.
3. (Amended) The method according to claim 1, wherein the at least one source of hypochlorite anion comprises at least one of metal hypochlorites or hypochlorous acid.
5. (Amended) The method according to claim 1, wherein the at least one source of hypochlorite anion [source] comprises chlorine dioxide.
6. (Amended) The method according to claim 1, wherein the at least one source of peroxide and the at least one source of hypochlorite anion are administered sequentially.
7. (Amended) The method according to claim 6, wherein the at least one source of peroxide and the at least one source of hypochlorite anion are administered through at least one [conventional] syringe and at least one needle.
8. (Amended) The method according to claim 1, wherein the at least one source of

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peroxide and the at least one source of hypochlorite anion are administered simultaneously.

9. (Amended) The method according to claim 8, wherein the at least one source of peroxide and the at least one source of hypochlorite anion are delivered through at least one dual lumen catheter.

12. (Amended) The method according to claim 1, wherein the administering of at least one of the at least one source of peroxide and the at least one source of hypochlorite anion is performed upstream of a blood flow to the target site and the blood flow carries at least one of the at least one source of peroxide and the at least one source of hypochlorite anion to the target site.

31. (Amended) The method according to claim 30, wherein at least one of the aqueous solutions comprising the at least one source of peroxide [source] and the at least one source of hypochlorite anion further comprises at least one pharmaceutically acceptable excipient.

36. (Amended) A method of treating a target site in or on a mammal, comprising: administering at least one source of singlet oxygen, wherein the at least one source of singlet oxygen comprises superoxide.

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